UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,347	11/14/2003	Joel Richard	017751-042	4071

21839 7590 10/04/2007

BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
10/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com
debra.hawkins@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/714,347	RICHARD ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-15,17,18 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15,17,18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 07/16/2007 are acknowledged.

2. Claims 3, 16 and 19 were cancelled. Claims 1, 4-10, and 13 were amended.

3. Claims 1, 2, 4-15, 17-18, and 20 are included in the prosecution.

Response to Arguments

Objection to claim 13

4. Applicant's correction of the typo in claim 13 is acknowledged. The objection of 03/16/07 is withdrawn.

Rejection of claim 16 under 35 USC § 112, Second Paragraph

5. Applicant's cancellation of claim 16 renders the rejection under 35 USC § 112, Second Paragraph moot.

Rejection of claims 1-13 and 15-20 under 35 USC § 103(a)

6. Applicant's arguments, see Page 6, filed 07/16/2007, with respect to the rejection of claims 1-13 and 15-20 under 35 USC § 103(a) as being unpatentable over Jason et al. (US 5,540,927) in view of Guerin et al. (WO 99/38945) have been fully considered but are not persuasive.

Applicant also argues that plant proteins are often impure, and the present inventors have discovered a method involving a solubilization step of the plant protein, which may be realized in a medium with a specific pH (between 2 and 7). Guerin teaches deionized water as a component of the emulsion containing soya protein (Col. 9, Example 1, line 11). Since the pH of deionized water is generally known to be

between 6.5 and 7, the solubilization, the limitation of solubilizing a plant protein in a medium with pH between 2 and 7 is met by the prior art reference.

Applicant argues that if the chosen pH is below the isoelectric pH of the plant protein, then the protein is used as a cationic polyelectrolyte in the complex coacervation process whereas when the chosen pH is above the isoelectric pH of the plant protein, then the protein is used as an anionic polyelectrolyte. However, Jason teaches the addition of an acid or water to adjust the pH. Therefore, one skilled in the art can readily manipulate the isoelectric pH of a plant protein. The plant protein can then be used as either a cationic polyelectrolyte or an anionic polyelectrolyte.

Examiner agrees with applicant's argument that Jason does not teach or suggest using plant proteins for coacervation and that Guerin does not teach or suggest coacervation. However, Guerin teaches water dispersible granulates or encapsulation comprising plant polypeptides and polyelectrolytes. This teaching of Guerin is combined with the coacervation taught by Jason to make the instant invention obvious. Applicant argues that the examiner has constructed a typical hindsight reconstruction of the invention, the references are combined, and there is no motivation to combine these two references.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references is provided by the general knowledge of the concern of gelatin products (especially regarding BSE or bovine spongiform encephalopathy) and the common practice in the field of pharmaceutical industry to replace these gelatin products with plant or vegetable sources.

Regarding the combination of references, all the claimed elements are found in Jason and Guerin and one skilled in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. -, 82 USPQ2d 1385 (2007).

Therefore, the rejection of 3/16/07 is maintained.

Rejection of claim 14 under 35 USC § 103(a)

7. Applicant's arguments, see Page 7, filed 07/16/2007, with respect to the rejection of claim 14 under 35 USC § 103(a) as being unpatentable over Jason et al. (US

5,540,927) in view of Guerin et al. (WO 99/38945), and further in view of Lee et al. (J. Appl. Polymer Science 1997) have been fully considered but are not persuasive.

Applicant argues that the Lee reference does not remedy the deficiencies of Jason and Guerin. However, the Lee reference is used to provide the teaching of acetic anhydride as a hardening agent for the microcapsule and is combined with the coacervation microcapsule teaching of Jason and plant protein encapsulation teaching of Guerin.

Therefore, the rejection of 3/16/07 is maintained.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-13, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jason et al. (US 5,540,927) in view of Guerin et al. (WO 99/38945).

Please note that Guerin et al. has a WIPO (WO 99/38945) publication date of 01/22/1999. Since the English translation was not available, the corresponding US patent (US 6,624,136) is being used in this instant rejection as a reference for the convenience.

The claimed invention is drawn to a method of producing microcapsules, comprising complex coacervation of a plant protein and a polyelectrolyte about the material to be encapsulated. The microcapsules made by this method are claimed along with their use in pharmaceutical, veterinary, cosmetic, agrofood, chemical or biomedical compositions.

Jason et al. (US 5,540,927 or US '927 hereafter) teaches a process of microencapsulation of materials by complex coacervation. The microcapsules comprise gelatin and polyaspartic acid, the latter provides the counter ion to the gelatin (Abstract). Following coacervation, the wall of the microcapsule is hardened by crosslinking (Abstract). The capsule walls are cross-linked by reaction with an aldehyde, commonly glutaraldehyde (Col. 2, lines 65-67) or "inorganic salt" (Col. 4, lines 24-27). The process includes dissolving the gelatin in a suitable solvent (Col. 4, lines 1-3).

US '927 does not teach microencapsulation of materials using plant proteins.

Guerin et al. (WO 99/38945, US '136 hereafter) teaches water dispersible granulates comprising plant polypeptides and polyelectrolytes.

Regarding instant claim 3, which requires solubilizing the plant protein in an aqueous medium at a pH between 2 and 7. A person having ordinary skill in the art would adjust the pH of the aqueous medium in order to ensure that the plant protein dissolved. The further limitations of centrifuging the solution and mixing the supernatant with the polyelectrolyte solution (of opposite charge) are well known in the art of coacervative microencapsulation. US '927 teaches the addition of polyaspartic acid or salt, which "provides ions of opposite electric charge than the gelatin" (Col. 4, lines 7-9).

The process disclosed in claim 4 of the instant application increases the soluble plant proteins in the microcapsules. A person with ordinary skill in the art would, during the process of routine optimization, vary the amount of soluble plant protein in the microcapsules, by either adding more plant protein to the supernatant or diluting the solution.

Regarding instant claims 5 and 6, US '927 teaches the "addition of an acid to adjust the pH ... or by adding sufficient water or both" (Col. 4, lines 10-13). Therefore, adjusting the pH to use the plant protein of the instant application either as a cationic polyelectrolyte or an anionic polyelectrolyte would be obvious to one skilled in the art.

Regarding claims 9 and 10 of the instant application, US '927 teaches (from reference US 4,803,168) microcapsules "formed from polyanionic polymers such as polyaspartic acid or polyglutamic acid and chitosan" (Col. 1, lines 45-48). US '927 teaches "in the complex coacervation process gelatin having a high iso-electric point and gum arabic containing many carboxyl groups are added to a core-containing suspension at relatively low pH above 35°C. The gelatin and gum arabic react to form microdroplets of polymer coacervate ..." (Col. 1, line 65 to Col. 2, line 3).

Regarding instant claims 11-13, US '927 teaches that capsule walls are "cross linked by typical prior art means such as reaction with an aldehyde, commonly glutaraldehyde" (Col. 2, lines 65-67).

Regarding instant claims 7 and 8, US '136 teaches plant proteins originating from "pea, bean, lupin, ... lentil, ... cereal seeds ... of wheat, barley, ... corn, ... oat, ... soya..." (Col. 4, lines 26-36).

Regarding instant claims 18–20, US '927 teaches active materials such as "dyes, ... food products, ... flavors and essences, pesticides and herbicides, adhesives, visual indicators and pharmaceuticals" (Col. 3, lines 63-67). Therefore, the microcapsules containing these active materials would obviously comprise pharmaceutical, cosmetic, food, chemical or biomedical compositions.

A person having ordinary skill in the art at the time the invention was made would find it obvious to make the microcapsules formed by complex coacervation (as taught by US '927) and replace the gelatin with plant proteins (as taught by US '136). The motivation to do so is provided by the general knowledge of the concern of gelatin products (especially regarding BSE or bovine spongiform encephalopathy) and the common practice in the field of pharmaceutical industry to replace these gelatin products with plant or vegetable sources. The resulting plant based microcapsules comprising various active materials would be expected to have utility in pharmaceutical, and chemical areas.

10. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Jason et al. (US 5,540,927), in view of Guerin et al. (US '136), and further in view of Lee et al. (J. Appl. Polymer Science 1997).

The teachings of US '927 and US '136 are stated above. The difference not taught in US '927 in view of US '136 is the use of acetic anhydride as the hardening agent.

Lee et al. teach the claim limitation of hardening the microcapsule containing the cationic polyelectrolyte chitosan by using acetic anhydride as the hardening agent

(Journal of Applied Polymer Science 1997). Lee et al. teach that "chitosan, a cationic polysaccharide, was ... deacylated ... and followed by a homogenous reacylation with acetic anhydrides" (Abstract). It is further taught that polyelectrolyte complexes are formed when chitosan is complexed with an anionic polysaccharide (like sodium alginate) and drug microencapsulation was the application of the polyelectrolyte complexes produced (Abstract). Typically the crosslinking agent is an aldehyde or inorganic salt" (Col. 4, lines 24-27). Therefore, the acetic anhydride would be obvious to one skilled in the art to use as a crosslinking agent with the chitosan in the microcapsules when US '927 in view of US '136 is taken in further view of the teaching of Lee (1997). The motivation to combine is provided by US '927, which teaches that "to harden the gelatin microcapsules a cross linking agent is introduced into the emulsion which reacts with the gelatin.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600